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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,281	05/29/2001	Heinz Kohler	411.35629PC2	5172

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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/03/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,281

Applicant(s)

KOHLER, HEINZ

Examiner

Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
2. Claims 1-26 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-20, drawn to a method of creating a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **cellular receptor** and wherein the **peptide is a specific hormone**, and a fusion gene encoding said fusion protein, classified in Class 435, subclass 69.1, Class 536, subclass 23.1.
 - II. Claims 1-20, drawn to a method of creating a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **cellular receptor** and wherein the **peptide is a specific ligand for a specific cytokine** and a fusion gene encoding said fusion protein, classified in Class 435, subclass 69.1, Class 536, subclass 23.1.
 - III. Claims 1-20, drawn to a method of creating a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **cellular receptor** and wherein the **peptide is a specific binding site derived from natural ligand for a specific cellular receptor**, and a fusion gene encoding said fusion protein, classified in Class 435, subclass 69.1, Class 536, subclass 23.1.
 - IV. Claims 1-20, drawn to a method of creating a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **membrane structure on a normal cell or on tumor cells** and wherein the **peptide is a specific hormone**, and a fusion gene encoding said fusion protein, classified in Class 435, subclass 69.1, Class 536, subclass 23.1.
 - V. Claims 1-20, drawn to a method of creating a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **membrane structure on a normal cell or on tumor cells** and wherein the **peptide is a specific ligand for a**

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specific cytokine, and a fusion gene encoding said fusion protein, classified in Class 435, subclass 69.1, Class 536, subclass 23.1.

- VI. Claims 1-20, drawn to a method of creating a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **membrane structure on a normal cell or on tumor cells** and wherein the **peptide is a specific binding site derived from natural ligand for a specific cellular receptor**, and a fusion gene encoding said fusion protein, classified in Class 435, subclass 69.1, Class 536, subclass 23.1.
- VII. Claims 21-26, drawn to a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **cellular receptor** and wherein the **peptide is a specific hormone**, and a composition comprising said fusion protein classified in Class 424, subclass 192.1.
- VIII. Claims 21-26, drawn to a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **cellular receptor** and wherein the **peptide is a specific ligand for a specific cytokine**, and a composition comprising said fusion protein classified in Class 424, subclass 192.1.
- IX. Claims 21-26, drawn to a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **cellular receptor** and wherein the **peptide is a specific binding site derived from natural ligand for a specific cellular receptor**, and a composition comprising said fusion protein classified in Class 424, subclass 192.1.
- X. Claims 21-26, drawn to a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **membrane structure on a normal cell or on tumor cells** and wherein the **peptide is a specific hormone**, and a composition comprising said fusion protein classified in Class 424, subclass 192.1.
- XI. Claims 21-26, drawn to a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **membrane structure on a normal cell or on tumor cells** and wherein the **peptide is a specific ligand for a specific cytokine**, and a composition comprising said fusion protein classified in Class 424, subclass 192.1.
- XII. Claims 21-26, drawn to a fusion protein made of (1) an antibody and (2) a peptide wherein the antibody is specific for a specific **membrane structure on a normal cell or on tumor cells** and wherein the **peptide is a specific binding site derived from natural**

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ligand for a specific cellular receptor, and a composition comprising said fusion protein classified in Class 424, subclass 192.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups (I-VI) and Groups (VII-XII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products as claimed can be used in materially different process such as making antibody or screening assays. Therefore, they are patentably distinct.

Inventions of Groups I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of making distinct fusion protein differ with their respect to their starting materials, process steps and endpoints. Therefore, they are patentably distinct.

Inventions of Groups VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products as claimed differ with respect to structure, physiochemical properties and different effects. Therefore, they are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.
5. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121 to elect:
If Group I, II, III, IV, V, or VI is elected, the Applicant is required to elect a specific method of creating a fusion protein made up of (1) **a specific nucleic acid sequence encoding a specific antibody that binds to a specific cellular receptor, or a specific membrane structure**, and (2) **a specific nucleic acid sequence encoding the specific hormone, ligand for cytokine or the binding site derived from natural ligand for a specific cellular receptor**. These nucleic

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acids encoding the different antibodies differ with respect to their structure and binding specificity and these nucleic acids encoding the specific peptide differ with respect to their structure, biological function, and effects.

If Group VII, VIII, IX, X, XI or XII is elected, the Applicant is required to elect a specific fusion protein made up of (1) **specific antibody that binds to a specific cellular receptor, or a membrane structure**, and (2) **a specific hormone peptide, a specific peptide ligand for cytokine or a specific peptide binding site derived from a natural ligand for a specific cellular receptor**.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18, and 21 are generic.
7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.
9. Due to the complexity of the claimed invention an oral restriction was not made.

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10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.
12. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

June 2, 2003


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600